Drug Coverage Policy

Effective Date.....6/15/2025
Coverage Policy Number.....IP0150
Policy Title..... Cosela

Oncology (Injectable) – Cosela

- Cosela™ (trilaciclib intravenous infusion – G1 Therapeutics)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW
Cosela, a cyclin dependent kinase (CDK) 4/6 kinase inhibitor, is indicated to **decrease the incidence of chemotherapy-induced myelosuppression** in adults when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (SCLC).[1]

The recommended dose of Cosela is 240 mg/m^2 per dose.[1] Cosela is administered prior to the start of chemotherapy on each day chemotherapy is given.[1] During Cycle 1 of the three Cosela pivotal studies, primary prophylactic granulocyte-colony stimulating factor (G-CSF) and erythropoiesis-stimulating agent (ESA) use was prohibited. Both ESAs and prophylactic G-CSF were allowed from Cycle 2, if clinically indicated. Therapeutic G-CSF, red blood cell, and platelet transfusions were allowed at any time during the studies as clinically indicated.

Guidelines

Cosela is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):[2,3]

- **Hematopoietic Growth Factors:** NCCN guidelines (version 1.2025 – October 11, 2024) recommend Cosela as a prophylactic option to decrease the incidence of chemotherapy-induced myelosuppression when administered before (prophylactic granulocyte colony stimulating factor [G-CSF] may be administered after cycle 1) platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage SCLC (category 2A). It is also recommended as a prophylactic option to decrease the incidence of anemia and red blood cell transfusions when administered before platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage SCLC (category 2B).[2]
- **Small Cell Lung Cancer:** Under supportive care, the NCCN guidelines (version 4.2025 – January 13, 2025) note that Cosela or G-CSF may be used as prophylactic options to decrease the incidence of chemotherapy-induced myelosuppression when administering platinum/etoposide ± immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage SCLC (category 2A).[3]

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POLICY STATEMENT

Prior Authorization is required for prescription benefit coverage of Cosela. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cosela as well as the monitoring required for adverse events and long-term efficacy, approval requires Cosela to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Cosela is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Small Cell Lung Cancer.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D, E and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has extensive-stage disease; AND
   - **C)** The medication is used to decrease the incidence of chemotherapy-induced myelosuppression; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** Patient will be receiving a platinum (carboplatin or cisplatin) and etoposide-containing chemotherapy regimen; OR
     - **ii.** Patient will be receiving a topotecan-containing regimen; AND
   - **E)** According to the prescriber, during the first cycle of chemotherapy, Cosela will not be co-administered with a granulocyte-colony stimulating factor (G-CSF) or an erythropoiesis-stimulating agent (ESA); AND

F) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve one dose (240 mg/m^2) administered as an intravenous infusion for every day the chemotherapy regimen is given.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Cosela for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9078	Injection, trilaciclib, 1 mg (Code deleted 09/30/2021)
J1448	Injection, trilaciclib, 1 mg

References

1. Cosela® intravenous infusion [prescribing information]. Durham, NC: G1 Therapeutics.; February 2024.
2. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 10, 2025.
3. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – January 13, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 10, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Name Change: Updated** Policy Name from "Trilaciclib Injection" to "Oncology (Injectable) – Cosela." **Small Cell Lung Cancer: Added** dosing information.	07/15/2024
Selected Revision	**Small Cell Lung Cancer:** Added criterion that during the first cycle of chemotherapy, Cosela will not be co-	1/15/2025

	administered with a colony stimulating factor or an erythropoiesis-stimulating agent, per the prescriber.	
6/15/2025	No criteria changes.	6/15/2025

The policy effective date is in force until updated or retired.